ADDITIONAL RESIDUE TESTING PROGRAM FOR FRESH MEAT EXPORTING TO THE EU

The EU Additional Residue Testing Program is outlined in the European Union Guidelines located in the Export Requirement library (http://www.fsis.usda.gov.) This program was initiated in 1989, under the responsibility of FSIS, International Programs, Export Coordination Division, with technical input from the Residue Staff. All red meat slaughter establishments approved for export of meat and/or offals to the EU are required to participate in the program. In 1996, the EU modified their residue control requirements for Member States, as well as for third countries. These requirements, which are reflected in Council Directive 96/22/EC and 96/23/EC, became effective July 1997. The United States has incorporated these modifications into the EU Additional Residue Testing Program.

Currently, the Office of Policy, Program Development and Evaluation (OPPDE), International Policy Staff (IPS) coordinates the additional testing program for products destined to the EU. Technical assistance is provided from the Office of Field Operations, Technical Service Center (Import/Export Control Staff and the Residue Operations Staff), the Office of Public Health and Science (OPHS) and the Agricultural Marketing Service (AMS.) FSIS continues to progress the discussions with the EU on equivalence of the residue control programs.

Effective March 1999, AMS, Science and Technology Program (S&T) initiated an oversight program of the laboratories conducting analytical residue chemistry for the EU program at the request of FSIS. The only laboratory qualified under this program in North America is Maxxam Analytics, Inc., Missisauga, Ontario, Canada [(905) 8890-2555]. Additional laboratories interested in participating in this program should contact FSIS, OPPDE, IPS at (202) 720-6400 for additional information.

Effective February 2001, tissue samples collected under this program (except for thyreostats) will be sent to Maxxam Analytics, Inc. On a <u>temporary</u> basis, the samples collected for thyreostats will be sent to the Veterinary Faculty Laboratory-Gent University, Gent, Belgium [+32.9.264.74.60.]

The following steps outline the existing program:

1. Roles and responsibilities.

<u>AMS, Science and Technology Division and FSIS, OPHS:</u> Responsible for technical assistance, analytical and monitoring components to assess and oversee the analytical performance of the laboratories participating in the EU "Additional Residue Program."

OPPDE, IPS: Responsible for negotiating the development of equivalence of the residue control program with the European Union. Until an agreement is reached, IPS will continue to oversee the current program, working cooperatively with the Technical Service Center (TSC) to monitor the number of samples requested,

collected and analyzed and submitting results to the EU. IPS is also responsible for approving any modifications to the testing categories and sample frequencies.

OFO, TSC, Import/Export Staff: Responsible for providing technical support and interpretation to the industry, as well as coordinating the addition or removal of approved slaughter establishments for the EU.

OFO, TSC, Residue Operations Staff: Responsible for monitoring the monthly sampling regime, as well as the results of the residue analyses of the EU program. Will initiate FSIS follow-up of violative positive results by scheduling additional sampling, if warranted, and appropriate notification to the Food and Drug Administration and the producer. Upon receipt of the analytical results from the laboratories, ROS will provide a list of the establishments shipping samples to each laboratory.

OPHS, Laboratory Sample Data Management Staff (LSDMS): Responsible for distributing the sample request forms to participating slaughter establishments, as well as providing detail report to OFO/TSC, OPPDE/IPS and the participating laboratories.

- 2. **Participation in the program.** All slaughter establishments approved for export to the EU are required to participate in the additional residue program. The TSC, Import/Export Coordination Staff will coordinate the addition or removal of an approved slaughter plant. Once a slaughter establishment becomes eligible to ship to the EU, the TSC communicates this to OPHS/LSDMS in writing. The slaughter establishment must advise OFO/TSC if it operates on a seasonal basis, so that samples can be adjusted accordingly. Any changes to this designation must be provided to the TSC, who will forward the information to OPHS.
- 3. **Sample requests.** Sample request forms (FSIS form 10,210-3) are preprinted and distributed by OPHS, FHSD periodically. These forms are mailed directly to the Inspector-In-Charge (IIC) at the designated establishment from FSIS/Washington, D.C. The information on the form includes the specified timeframe the sample is to be collected, the designated contract laboratory performing the analyses, the target tissue(s), and the compounds to be analyzed. Compounds are grouped together into "testing categories", identifying the current compound/tissue matrix. A summary of the analyte testing profile, including the compounds, the method of detection, the target tissue, species to be tested and the target limit of detection, along with the EU action levels are available upon request from FSIS/OPPDE/IPS.

The FSIS IIC will collect and secure the requested sample(s) and will express mail these to the appropriate laboratory overnight. If no sample is available or the sample request form arrives after the scheduled collection date, the form is returned to the TSC so that the sampling frequency can be adjusted, if necessary. OPHS will provide a monthly "detail" list or a summary of all the scheduled samples to the TSC, Residue Operations Staff, when the sample request forms are mailed. In addition, a summary

of the samples destined to each laboratory will be provided to OPPDE/IPS and the participating laboratory.

- 4. **Number of samples** (**identification of compounds**). The annual number of samples targeted per compound is listed in the EU Requirements located in the Export Library. This sampling frequency is based on the volume of product exported to the EU the previous year. Distribution of the number of samples targeted for each compound is based on the requirements as outlined in EU Directive 96/23/EC.
- 5. Reporting results. The independent laboratories must report summaries of the analytical reports to FSIS, OPPDE, IPS, who will forward these results to OFO, TSC, Residue Operations Staff. This staff will forward these results to the IIC in the slaughter establishment. Violative positive reports must be provided immediately to FSIS, so that appropriate action can be taken. The laboratories may also provide copies of the results to the approved slaughter plant, once the summary of scheduled samples is provided to them. Annual summaries of these results are provided to the EU, which are transmitted by IPS.